

Remarks

Upon entry of the amendment, claims 12-16, 18, 71, and 73-77 will be pending in the application. Claims 65-70, 72 and 78-91 have been cancelled. Support for the amendment to claim 12 requiring at least 90% identity appears in the specification at, e.g., page 20, lines 15-20.

Claims 14 and 15 have been amended to correct various informalities. The specification has been amended at page 2 line 5 as requested by the Examiner to replace “ligands” with “receptors”. No new matter has been added.

Applicants submit an alignment of SEQ ID NO:4 (recited in the pending claims) and the sequences disclosed in references C1-C11, C13, and C19, included in various information disclosure statements submitted in the application. (Exhibit 1).

Rejections under 35 USC 112, second paragraph

Claims 14, 15, 18 and 78-91 are rejected as indefinite. Claims 78-91 are canceled.

Applicants traverse the rejection as applied to the remaining claims as amended.

The Examiner states that claim 14 is indefinite for reciting “operably linked to.” Applicants have amended claim 14 to delete the term “operably”.

The Examiner states that claim 15 is indefinite for reciting “*an* immunoglobulin molecules,” and for reciting “or” within a Markush group. Applicants have amended claim 15 to correct these informalities.

The Examiner states that claim 18 is indefinite for insufficiently identifying the CRF2-12 polypeptide. Applicants have amended claim 18 to specify that the claimed kit comprises in one or more containers the CRF2-12 polypeptide of claim 1.

Reconsideration and withdrawal of the rejections for indefiniteness is requested.

Rejections under 35 USC 112, first paragraph

Claims 12, 14-16, 65-71, and 76-91 are rejected for overbreadth. Claims 65-70 and 78-91 are cancelled. The rejection is traversed to the extent it is applied to the claims as amended.

The Examiner acknowledges that the specification is enabling for claims drawn to a polypeptide with at least 90% identity to the recited sequence (see paragraph bridging pages 3 and 4 of the Office Action). Accordingly, applicants have amended claim 12, from which the remaining claims subject to the rejection depend, to specify that the polypeptide comprises an amino acid sequence with at least this level of identity to SEQ ID NO:4. Therefore, this rejection can be withdrawn.

Claims 78-91 are further rejected for lack of written description. These claims have been cancelled. Therefore, this rejection of claims 78-91 is moot.

Rejections under 35 USC 102(e)

Claims 12-16, 18, 65-70, 72-86, and 88-91 are rejected as anticipated by Agarwal et al., U.S. 2003/0129862 A1 (“Agarwal”). Claims 65-70, 72 and 78-91 have been cancelled. The rejection is traversed to the extent it is applied to the remaining claims as amended.

The pending claims are drawn to, or based on, the polypeptide sequence corresponding to SEQ ID NO:4. The Examiner contends that Agarwal discloses a sequence, which it refers to as SEQ ID NO:42, that is 100% identical to Applicants’ SEQ ID NO:4. However, as is explained below, Agarwal does not constitute prior art to the claimed invention because the invention of claims 12-16, 18, and 72-77 is disclosed in a priority application that is earlier in time to the earliest disclosure of SEQ ID NO:42 in Agarwal or the applications from which Agarwal claims

priority.

The filing date of the present application is January 14, 2002. The application claims priority to USSN 60/261,442 (“the ‘442 application”), filed January 12, 2001; USSN 60/267,021 (“the ‘021 application”), filed February 6, 2001; and USSN 60/270,835 (“the ‘835 application”), filed February 23, 2001.

The ‘021 application discloses in Table 4, page 7 a polypeptide sequence named SEQ ID NO:4 that is identical to SEQ ID NO: 4 of the present application. The subject matter of claims 12-16, 18, and 72-77 is further disclosed at, e.g, page 2, lines 4-8, page 12, lines 16-20, page 32, lines 2-4, and throughout the claims of the ‘021 application. Thus, these claims are entitled to a filing date of no later than that of the ‘021 application, which is February 6, 2001.

Agarwal was filed as a US national phase application of PCT/US01/19929, filed June 22, 2001 and which claimed priority to USSN 60/213,161 (“the ‘161 application”), filed June 22, 2000, and USSN 60/213,156 (“the ‘156 application”), also filed June 22, 2000.

The ‘161 application discloses nucleic acid and corresponding polypeptide sequence information on pages 18, 43, 66, 91, 116, 140, 164-165, 189-191, 216-217, and 242-247.¹ However, none of the sequences disclosed in the ‘161 application corresponds to SEQ ID NO:42 of the Agarwal application.

The ‘156 application shows nucleic acid and corresponding polypeptide sequence information on pages 19, 43-44, 68, 92, 116, 140, 165, 189, 213, and 238.² None of the sequences disclosed in the ‘156 application are identical to the amino acid sequence of SEQ ID NO:42, although one sequence (SEQ ID NO:2) on page 165 of the ‘156 application includes a portion of the amino acid sequence of SEQ ID NO: 42 of Agarwal. An alignment of SEQ ID NO:4 of the present application

¹ A true copy of the certified ‘161 application is enclosed as Exhibit 2.

and SEQ ID NO:2 of the '156 application is provided as Exhibit 4.

An amino acid sequence corresponding to SEQ ID NO: 42 of the pending claims (referred to as SEQ ID NO:42 of Agarwal) is thus absent in both the '161 application and the '156 application.

The first disclosure of the amino acid sequence of SEQ ID NO:42 instead appears in Agarwal itself, which was filed as a US national application of PCT/US01/19929, filed June 22, 2001. All of the pending claims require a polypeptide with the amino acid sequence of SEQ ID NO:4. Therefore, even if Agarwal is considered to describe Applicants' claimed invention, it does so only as of June 22, 2001, which is later than the February 6, 2001 filing date of the '161 application, and which is the date to which Applicants' claims are entitled. Agarwal is therefore not prior art to the claimed invention, and it is not available as a reference under 35 USC 102(e).

In view of the foregoing comments, reconsideration and withdrawal of the rejections for anticipation is requested.

On the basis of the foregoing amendment and remarks, Applicants respectfully submit, that the pending claims are in condition for allowance. If there are any questions regarding this amendment and/or these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

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Respectfully submitted,

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² A true copy of the certified '156 application is enclosed as Exhibit 3.